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1 RECORD OF ORAL HEARING
2 UNITED STATES PATENT AND TRADEMARK OFFICE
3

4

5 BEFORE THE BOARD OF PATENT APPEALS
6 AND INTERFERENCES
7

8

9 *Ex parte* SUONG-HYU HYON
10 and MASANORI OKA
11

12

13 Appeal 2010-006736 and 2010-006737
14 Application 10/643,673 and 10/643,674
15 Technology Center 1700
16

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18 Oral Hearing Held: October 20, 2010
19

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21 Before ALLEN R. MACDONALD, MICHAEL P. COLAIANNI, and
22 KEN B. BARRETT, Administrative Patent Judges
23

24

25 ON BEHALF OF THE APPELLANTS:

26

27 DAVID L. SUTER, ESQUIRE
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1 The above-entitled matter came on for hearing on Wednesday,
2 October 20, 2010, commencing at 1:03 p.m., at the U.S. Patent and
3 Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Jennifer
4 O'Connor, Notary Public.

5 THE CLERK: Good afternoon. Calendar number 43, appeal
6 number 2010-006736, Mr. Suter.

7 MR. SUTER: Thank you.

8 JUDGE MACDONALD: Is this your first hearing, or have you
9 been here before?

10 MR. SUTER: It is -- I have had two hearings before, but many
11 years ago.

12 JUDGE MACDONALD: Okay. Well, I will walk through the
13 process.

14 MR. SUTER: Okay.

15 JUDGE MACDONALD: You have 20 minutes for each one,
16 so 40 minutes total.

17 MR. SUTER: Okay.

18 JUDGE MACDONALD: Use it any way you see fit.

19 MR. SUTER: Okay.

20 JUDGE MACDONALD: If we interrupt you with lots of
21 questions, we will give you more time, okay.

22 MR. SUTER: Perfect, okay.

23 JUDGE MACDONALD: And you may begin any time that
24 you wish to.

25 MR. SUTER: I will get myself set up here, if I could, please.

1 So, I gather I've got -- that was one of my questions. The two
2 questions are obviously related, so we could serve -- okay. Sorry, waiting
3 for my computer to boot up here. And it's going through some update
4 operation.

5 (Pause.)

6 MR. SUTER: Well, tell you what. I am going to start
7 extemporaneously here, so -- it's going, but you know, just my luck, it
8 decides to go through some update process.

9 Anyway, I will talk about both these cases together. The issues
10 are essentially identical. I don't propose that they be treated the same,
11 necessarily, but the issues are close enough, really, that there is little sense in
12 necessarily dealing with them completely separately.

13 Just by way of background, both of these cases are, of course,
14 divisionals off of a single reissue application that was filed within two years
15 of the original filing date -- or issue date, I should say -- of the 626 patent.
16 The technology relates to ultra-high-molecular-weight polyethylene that's
17 used in making orthopedic implants, the bearing surface of the -- for, like, a
18 knee or a hip joint that the -- a metal component rides on another
19 component. And some joints have metal on metal. Most, or many preferred
20 joints, have plastic. And that plastic is ultra-high-molecular-weight
21 polyethylene.

22 The -- one of the issues that's been observed in the art for some
23 time is sort of improving the wear strength of the ultra-high polyethylene.
24 And the art had recognized that you can get improved wear properties by
25 cross-linking, and that cross-linking can be done by irradiation, like gamma
26 irradiation. The -- but that potentially creates issues, as well, in terms of

1 some properties are improved and some are not. And so there is a body of
2 art that relates to how to improve the polyethylene that's used in those joints,
3 and that is essentially the basis for the current invention.

4 The claims in both of these cases essentially relate to methods
5 of making ultra-high polyethylene -- involve radiation and then heating, and
6 then a pressure step. The -- there are, as I said -- sorry, I'm interrupting
7 myself, but while my computer lives I want to try to get back to where I
8 was -- okay.

9 The 626 patent was issued in January of 2001. And the reissue
10 was filed in May 2002, and characterized at the time -- it was filing as a
11 broadening reissue. The claims in the reissue, as filed, were addressed to a
12 number of embodiments that were not pursued in the original prosecution,
13 and there were sort of two groups of claims. There were in excess of 250
14 claims that were presented in this admittedly large reissue application.

15 Some of the claims related to, essentially, heat treatment of
16 irradiated polyethylene as a means of improving material properties. Then
17 there were additional claims that related to heat treatment plus pressure.

18 There was a 12-way restriction requirement that we
19 encountered; one group, of course, being the originally filed or issued
20 claims. Then, from that, we filed two divisional applications, which
21 have -- one, to essentially pursue embodiments that related to pressure, and
22 another to pursue the irradiation and heating embodiments.

23 The patentability of the original claims of the issued 626 patent
24 was confirmed, and claims in these reissues have been variously rejected on
25 art -- 112 issues and recapture at this point. There are now four pending
26 reissues, two of which are still in front of the Examiner, and then the two

1 that are before the board today. The two that are before the board today both
2 relate to the pressure claims.

3 Okay, now I'm going to talk about, initially, the 673
4 application, which is the hearing docket 6736. It presents two independent
5 claims which are, essentially, identical, except for the last step. And, again,
6 the process in question here is cross-linking an ultra-high molecular weight
7 article, heating the irradiated article to a compression deformable
8 temperature between 50 degrees below the melting point to the melting
9 point, but below the melting point, compression forming that heated article,
10 and then cooling the article while maintaining the deformation pressure.

11 Claim 139 -- that was Claim 140, but Claim 139 also has an
12 additional step of processing to form an implant. The two issues that
13 are -- remain in the case that are subject to appeal are the recapture
14 rejections, and then an obviousness rejection. The recapture is probably the
15 more difficult issue, in some sense, just because of the amount of arguing
16 that's gone back and forth. The obviousness issues, I think, are somewhat
17 more straightforward, although obviously we disagree with the Examiner's
18 position.

19 The Examiner has pointed to several elements of the claims that
20 we have that are broader than the corresponding elements in the issued 626
21 patent. And this is admittedly true, consistent with the fact that we have
22 started this as a broadening reissue.

23 As I'm sure you know, the analysis for recapture is a three-step
24 process following the Pannu v Storz case and In re Clement. Just quickly
25 running through those steps, you know, the first step is to determine in what
26 respect the claims are broader than those that were prosecuted and issued in

1 the original patent, determining whether those aspects are broader or -- I'm
2 sorry, really to subject matter that was surrendered during the original
3 prosecution. And then the third step, if both of those essentially yield -- lead
4 to a conclusion that there are broader aspects, then to determine whether the
5 claims are materially narrowed in other aspects, so as to avoid recapture.

6 We essentially agree with the Examiner that, as I said, that there
7 are elements of the claims that are broader than corresponding elements in
8 the 626 patent. The primary issue in this appeal, particularly for the first
9 case that I'm talking about, relates to the third step of the Pannu analysis.

10 But, you know, going back to the second step, you know,
11 we -- as we explore further in the brief, the present claims do not represent
12 an attempt to reopen the prosecution of the issued claims. Of course, we did
13 not amend those claims. We are claiming, in our view, alternative preferred
14 embodiments, consistent with what we would consider to be well-permitted
15 and conventional prosecution strategy for patents -- obviously, trying to
16 flesh out claims to a number of what we consider to be
17 commercially-preferred embodiments, not necessarily recapturing what we
18 had given up.

19 JUDGE MACDONALD: Excuse me -

20 MR. SUTER: Yes, sir?

21 JUDGE MACDONALD: You are not saying, though, these
22 were overlooked during prosecution?

23 MR. SUTER: I think some aspects of this invention were
24 overlooked. I think that will be true -- that will be more evident in the
25 second case than in the first case.

1 JUDGE MACDONALD: But weren't all of these
2 new -- subject matter of these new claims, wasn't that present in the original
3 claims in some form?

4 MR. SUTER: The -- of these claims?

5 JUDGE MACDONALD: The --

6 MR. SUTER: That is correct. In one form or another, that is
7 correct.

8 JUDGE MACDONALD: So how was it overlooked, if it was
9 present in the claim?

10 MR. SUTER: I think what was overlooked was claiming the
11 below-the-melting-point embodiment, which -

12 JUDGE MACDONALD: But melting point was certainly part
13 of the claims.

14 MR. SUTER: Melting point was part of the original claims.

15 JUDGE MACDONALD: So --

16 MR. SUTER: That is true.

17 JUDGE MACDONALD: So why would someone, in looking
18 at the original claim, think that a later statement that something was
19 overlooked was reasonable, when that subject matter was present and clearly
20 looked at by -- during prosecution in the original claims, when those claims
21 were filed? That was a consideration that was made to state the particular
22 ranges that were present in those claims for that subject matter.

23 MR. SUTER: The -- I believe that the original prosecution
24 focused on what was understood then to be the preferred embodiment, with
25 the very specific -- you know, but a broader range, with respect to the
26 temperature.

1 JUDGE MACDONALD: But a conscious decision was made
2 about the range for that item.

3 MR. SUTER: A conscious -

4 JUDGE MACDONALD: Whether it's irradiation or pressure or
5 temperature.

6 MR. SUTER: Well, indeed. I mean, obviously, conscious
7 decisions were made regarding the scope of the claims that were pursued in
8 the original prosecution.

9 JUDGE MACDONALD: But I am -- in addition, it is not just
10 that, but the subject matter was part of that decision, because it is present in
11 those claims in some form.

12 MR. SUTER: In some form it is, in the -- you know,
13 there -- you know, temperature was an element of that claim. The
14 temperature range that was originally prosecuted subsumed the range that we
15 are identifying now as a further preferred embodiment -- I mean, in the sense
16 that below the melting point, obviously, was an aspect of the range that went
17 from below to above the melting point. And of course, the pressure step, as
18 well.

19 So, I mean, you know, in -- broadly speaking, you are
20 absolutely right.

21 JUDGE MACDONALD: Well, the office and the MPEP has
22 taken a fairly specific definition for "overlooked." It sounds like you are
23 saying you don't agree with the Office's policy statement on that.

24 MR. SUTER: Well, I think the policy statement, as I
25 understand it, is -- you know, as I interpret "overlooked," it is -- in essence,

1 it's an aspect of the invention, as described in the specification, that was not
2 the specific focus of the original prosecution.

3 Now, overlooked, in the sense of -- you know, that they didn't
4 appreciate that they should have claimed that lower range, well, I would say
5 that's what occurred here. Overlooked in the sense that they understood the
6 technology, well, no. I mean, it was described. But I think the aspect of
7 what was overlooked here relates to, you know, the misapprehension of the
8 applicant at that point of, you know, having claimed all the embodiments
9 that he said he was rightfully entitled to have prosecuted, you know.

10 The technology and the discovery that underlies this invention,
11 you know, there are a number of aspects of that technology that relate to and
12 allow preferred material characteristics. And the focus of -- at that time was
13 obviously to try to claim a broader range of temperatures, not recognizing
14 that there are -- that there may be specific benefits or -- they recognize the
15 benefits, but not recognizing that they could have or should have claimed a
16 lower range.

17 JUDGE MACDONALD: I am assuming any cases -- you had
18 already mentioned that there were some cases -

19 MR. SUTER: Yes, yes.

20 JUDGE MACDONALD: -- that would point to -

21 MR. SUTER: Yes, and we have addressed the overlooked
22 aspect, as well, I believe, in the answer, at least in the second case.

23 JUDGE MACDONALD: Thank you.

24 MR. SUTER: Sure. Certainly. Focusing on the third step of
25 the Pannu analysis, we have focused in our brief and analysis in front of the
26 Examiner on the In re Clement formulation, which basically states that -- I

1 will quote here -- "if the reissued claims are as broad or broader in an aspect
2 germane to a prior art rejection, but narrower in another aspect completely
3 unrelated to the rejection, the recapture rule bars the claim," which we
4 interpret or sort of reformulate logically to say then that that recapture rule
5 does not bar the claim if it's narrower in an aspect that is not completely
6 unrelated to the prior rejection.

7 So, in essence, a narrowing aspect that's offered in the reissue
8 claim must be somehow related to the rejection that was in the prior
9 prosecution, i.e. not completely unrelated. And so that's the -- that's been the
10 focus of our analysis in front of the Examiner.

11 As we've already discussed, of course, the key aspect of
12 narrowing is the temperature under which the compression is deformed.
13 And you know, the claims now require that compression to be done at a
14 temperature below the melting point of the ultra-high polyethylene. The
15 claims of the patent as filed and issued simply require a compression
16 deformable temperature. There is a dependant claim, as issued, that relates
17 to a range that goes 50 degree Centigrade below the melting point to 80
18 degrees higher than the melting point in this dependant claim.

19 Focusing on this lower end of the range, we think it's
20 significant, both from a legal and a technical sense. Certainly from a
21 technical perspective, it would seem fairly evident that, you know, the
22 processing of material properties of any material solid as polyethylene
23 would be affected by the temperature by which you perform the
24 compression. And certainly heating something and attempting to compress
25 it below its melting point is a different proposition than heating and
26 deforming a material at or above the melting point.

1 But from a legal perspective, we also think -- submit that
2 the -- you know, that this focusing on this temperature limitation is -- really
3 is germane, or would have been germane to the prosecution of the original
4 patent.

5 One of the focuses of the rejections in the initial
6 prosecution -- and, indeed, during this prosecution -- is on the Kitamaru
7 patent, which is discussed in the brief and in the record. It's 3886056. That
8 patent discloses a process for making ultra-high-molecular-weight fibers,
9 films, and sheets by heating above the melting point and applying pressure.

10 The claims in the -- in this application were, in fact, rejected as
11 being anticipated in Kitamaru. Kitamaru was also the basis of rejection
12 during the prosecution of the original claims. In the current prosecution, the
13 rejection was withdrawn with the Examiner specifically pointing to the
14 temperature as the basis for the distinction.

15 I will quote the Examiner here, that this rejection of claims 104,
16 109, the claims that were then pending, were -- as being anticipated as
17 withdrawn -- Kitamaru -- teach extending ultra-high-molecular-weight
18 polyethylene under pressure in the molten state, while the
19 instant -- claim -- the method is now limited to temperatures between 50
20 degrees lower than the melting point, and the melting point of the ultra-high.

21 So, we would submit, in view of that prosecution history alone,
22 it is -- it would seem clear that the temperature range here is something that
23 would not be completely unrelated to the rejections that were addressed in
24 the original prosecution of the 626 patent.

25 Now, I would like to move on to the obviousness rejections in
26 this case.

1 MR. BARRETT: Before we move on -

2 MR. SUTER: Certainly.

3 MR. BARRETT: Reissue Claim 104. You had mentioned
4 earlier that the reissue of claims basically fell into two groups -

5 MR. SUTER: Yes.

6 MR. BARRETT: -- the heat treating, and then the heat treating
7 plus pressure.

8 MR. SUTER: Correct.

9 MR. BARRETT: What are you calling the pressure in Claim
10 104, the compression step?

11 MR. SUTER: It is the compression step, yes.

12 MR. BARRETT: Okay. And that's to be distinguished from
13 the pressure step in dependant Claim 109?

14 MR. SUTER: Let me pull the claim here, and be sure.

15 (Pause.)

16 MR. SUTER: Well, no. It's -- there is two pressure -- it's the
17 same pressure step. Claim 109 basically says that the pressure is applied
18 during the heating step, as opposed to heating and then applying the
19 pressure.

20 As Claim 104 is laid out, you know, we have the cross-linking
21 heating, compression, and then cooling. The intent of Claim 109 is that
22 essentially steps B and C can be run concurrently.

23 MR. BARRETT: Okay.

24 MR. SUTER: The claims have been rejected as being obvious,
25 based on a combination of the Kitamaru reference that we already discussed,

1 this time as a secondary reference, in combination with patent 5030402,
2 Zachariades.

3 Zachariades discloses solid state deformation of ultra-high
4 polyethylene for making implants in a compression molding at temperatures
5 below the melting point. However, the process of Zachariades does not
6 disclose cross-linking the polyethylene until after that molding is deformed.
7 You know, the molding in that process is essentially the molding that occurs
8 when the product is -- when the implant is made. It does discuss that
9 radiation can be done after the molding.

10 The Examiner basically used the teaching of irradiation prior to
11 extension in Kitamaru as the basis for saying that the irradiation could be
12 prior to the compression. And that would -- and so the combination of the
13 two in the Examiner's analysis led to a process that involved irradiation,
14 heating, and then compression.

15 The -- we -- one of the points that we want to underscore is that
16 these references are addressed as significantly different materials.
17 Zachariades, as I said, is addressed to orthopedic implants, whereas
18 Kitamaru is broadly stated to relate to fibers, films, and sheets. And to the
19 extent that they describe sort of specific embodiments and benefits, they are
20 looking at improved properties, such as melting point and transparency for
21 use in bottles and containers.

22 We would submit that one of skill in the art would not
23 necessarily combine these references for either purpose, either for making
24 containers -- you have a plastic that's used for implants, you have a plastic
25 that's used for other purposes, fibers, films, and sheets. Combining them

1 doesn't necessarily -- wouldn't be obvious for an ordinary artisan to do for
2 either purpose.

3 The Claim 139, then, is even further distinguished, because,
4 unlike Kitamaru, then it specifically talks about the final process step of
5 making the implant itself. And, indeed, you know, that's certainly a much
6 different process than what is in Kitamaru.

7 Our -- in our view, one reaches this invention essentially by sort
8 of -- by picking and choosing certain features of Kitamaru. Kitamaru does,
9 indeed, disclose cross-linking before its extension, the extending pressure
10 that's applied there to make films and sheets. But Kitamaru also teaches, as
11 we said before -- has nothing to do with applying pressure below the melting
12 point. So, if one follows -- if one is to follow the teachings of Kitamaru, you
13 know, the rejection relies on sort of selecting the feature of cross-linking
14 before extension, but ignoring the fact that Kitamaru will tell you to do that
15 above the melting point.

16 So, in our view, you know, the combination of these references
17 is inconsistent with the process of the primary reference, which specifically
18 teaches you, in the context of orthopedic implants, to do the irradiation after
19 you've done the compression molding. And then it does that by, in our view,
20 arbitrarily selecting only some of the features of the secondary reference.
21 And there is no guidance in these references or their art, as we're aware of,
22 for making that combination, but for the disclosure of our own applicant.

23 Now, I want to then touch on the second -- move on to the
24 second case, which I said is very similar -- again, presents two independent
25 claims that differ primarily if Claim 84 is the broader -- I'm sorry, I got that

1 backwards -- claim -- yes, Claim 40 is the broader, and Claim 84 is
2 the -- further requires a step of processing the final block into an implant.

3 The principal -- there is two principal differences between the
4 subject matter of the two cases. This application, the 673 application,
5 discusses the application of pressure, but does not state it in terms of a
6 compression deforming pressure. The second point is that the process of the
7 673 application discusses cooling, but does not include the requirement of
8 maintaining the deformed state.

9 Again, we face essentially the same issues, recapture and
10 obviousness. There are two obviousness rejections here, but they are
11 essentially under the same analysis. The principal difference, really, in the
12 analysis of the two cases has to do with the recapture. And, in our view, the
13 claims in the second case are fundamentally directed to a different invention.
14 And in that regard, it just inherently isn't a recapture.

15 Looking specifically at step two of the Pannu analysis, we
16 would submit that, to the extent that there are elements of this claim that
17 are -- that correspond to elements in the 626 patent, and that these claims are
18 broader, they don't relate to subject matter because, again, it's a different
19 invention. Indeed, the claims of the pending reissue are broader by omitting
20 an element that was present in the prosecution of the original patent
21 of -- both as filed and as issued, and that's the element of requiring that the
22 pressure be applied -- or that the cooling is done while the pressure remains
23 applied to the polyethylene.

24 We spent some time in the brief and in prosecution, of course,
25 pointing to the restriction requirement in the Examiner's initial analysis,
26 where the claims are parsed into 12 different groups. And, indeed, these

1 claims, where the pressure was not maintained during cooling, were viewed
2 in the context of the restriction as being distinct. But beyond the procedural
3 aspect of the reissue, we would submit that this is a different invention
4 because, to the extent that it's broader, it's broader in a way that was never
5 part of the original prosecution.

6 Notably, as well, then, you know, the -- in that view I don't
7 think we even necessarily -- and the analysis would have to get to the third
8 prong of the Pannu analysis. But, of course, if we did, the analysis would be
9 much the same as it is in the other case, in the sense that this temperature
10 limitation, which exists in this case, indeed was germane to the prosecution
11 of the original claims in the consideration of the Kitamaru reference.

12 Notably, the Examiner's analysis we submit in this -- or, in fact,
13 both cases -- ignores the third prong. In the answer, the Examiner -- and I
14 will quote this -- says, "The limitation, with respect to subjecting the
15 cross-link polyethylene to pressure at a temperature below the melting point
16 required in the instant claims is considered to be significant narrowing, only
17 if the additional limitations of the patented claims are retained, rather than
18 broadened," which would suggest that, in that kind of analysis, there is no
19 way that you could have a broadening reissue, even if -- that did not contain
20 each and every element of the initial claims. And that, in our view, is not the
21 formulation of the law.

22 Certainly Pannu and In re Clement allow how you can have
23 broader aspects, as long as there is a materially narrowing element. And, as
24 we said, we do believe that the temperature limitation in both these cases is
25 materially narrowed. And, indeed, in this case, in the second reissue, it's not
26 even the same invention.

1 The obviousness analysis in this case, then, is essentially
2 identical to the other case. I am not going to go through that in further
3 detail. You know, again, in our view the combination of references, you
4 know, would not be done by the ordinary artisan, and that the -- that there is
5 an inconsistency in reading the two references together, that they would not
6 be -- that the combination is not apparent, and that one wouldn't be making
7 that combination for the purposes of either making an implant or making the
8 fibers and sheets that are disclosed in the Kitamaru reference.

9 So, with that, I think I am -- if you have got any questions, I
10 appreciate your time.

11 JUDGE MACDONALD: I have no questions.

12 MR. SUTER: Very good. Well, thank you very much. I
13 appreciate it.

14 JUDGE MACDONALD: Thank you.

15 MR. SUTER: Sorry for my computer delay.

16 Whereupon, at 1:35 p.m., the proceedings were concluded.

17